K103534

510(k) Summary
[As required by 21 CFR 807.92(c)]

JAN - 5 2011

1. Submitter's Name / Contact Person

Submitter:	TriReme Medical, Inc. 7060 Koll Center Parkway, Suite 300 Pleasanton, CA 94566
Contact Person:	Shiva Ardakani VP of RA/QA Phone: 925-931-1300 Ext 209 Fax: 925-931-1361
Date Prepared:	October 27, 2010

2. General Information

Trade Name:	GliderfleX™ PTA Balloon Catheter
Common/Usual Name:	Angioplasty Catheter
Classification Name:	Percutaneous Catheter (21 CFR 870.1250)
Product Code:	DQY / LIT
510(k) number:	
Predicate Devices:	NanoCross PTA Dilatation Catheter (K090849)
	EverCross .035" OTW PTA Dilatation Catheter (K082579)
	GliderXtreme PTA Balloon Catheter (K101062)

3. Intended Use

The GliderfleX™ PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries. NOT for use in the coronary or cerebral vasculature.

4. Device Description

The GliderfleX™ PTA Balloon Catheter is a standard balloon dilatation catheter with a braided shaft and an atraumatic, tapered and beveled tip. The device is compatible with commonly used accessories, including standard 0.014" and 0.018" guidewires and 5F introducer sheath (or 6F guide catheter). Overall catheter lengths are approximately 120 cm to 150cm.

The distal end of the catheter has a semi-compliant balloon that expands to known diameters (refer to compliance chart) at specific pressures. The balloon contains radiopaque markers to assist with positioning. The shaft is braid reinforced and has a lubricious hydrophilic coating. The proximal end of the device is a common PTA catheter connected to a plastic hub and strain relief. The hub is used to inflate the balloon; the luer connector is compatible with standard inflation devices.

The GliderfleX™ PTA Balloon Catheters are supplied sterile and intended for single use only.

5. Performance Data

Bench testing was performed to support a determination of substantial equivalence. Results from this testing provide assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use.
The following *in vitro* tests were performed:

- Balloon Rated Burst Pressure
- Balloon Inflation and Deflation
- Balloon Fatigue
- Catheter Body Strength (Bond Strength)
- Torsional Strength
- Catheter Diameter, Balloon Profile and Tip Configuration
- Balloon Compliance
- Trackability, Pushability
- Kink Resistance
- Device Interface Compatibility

6. Substantial Equivalence Comparison and Conclusion

All GliderfleX™ PTA Balloon Catheters are substantially equivalent to the predicate devices in design, materials, packaging, fundamental scientific technology, manufacturing, sterilization and intended use. Performance testing demonstrated that the GliderfleX™ PTA Balloon Catheter reliably achieved the desired effect and is safe for its intended use. No new questions of safety or effectiveness were identified during device testing. Therefore, All GliderfleX™ PTA Balloon Catheters are considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Regulatory Technology Services LLC
c/o Mr. Mark Job
Responsible Third Party Official
1394 25th Street NW
Buffalo, MN 55313

JAN - 5 2011

Re: K103534
GliderfleX™ PTA Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II (two)
Product Code: DQY
Dated: December 16, 2010
Received: December 17, 2010

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

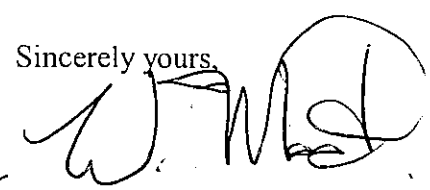
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103534

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Device Name: GliderfleX™ PTA Balloon Catheter

Indications For Use:

The GliderfleX™ PTA Balloon Catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-politeal, and renal arteries. NOT for use in the coronary or cerebral vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103534